1F100

RMRS Rocky Mountain Remediation Services, L.L.C.
. . . protecting the environment

INTEROFFICE MEMORANDUM

DATE: August 28, 1996

TO: DISTRIBUTION

FROM: Mic Prochazka, Quality Assurance, Bldg. T893B, X4747

SUBJECT: REVIEW OF RMRS-QA-03.01 QUALITY CONDITIONS REPORT
DRAFT C - TMP-002-96

Action: Review and Comment

RMRS is implementing a corrective action program to address deficient conditions under RMRS responsibility. The intent of the program and the attached Quality Condition Report (QCR) procedure is to implement internal controls for resolving problems identified from internal audit, management assessment, self evaluation as well as External audit/assessment by DOE, Kaiser-Hill.

The plan is for this procedure to help identify conditions adverse to quality and serve to complement and interact with other site wide corrective action systems. The interaction with other systems allows RMRS to gather deficient conditions into a single data system, and manage corrective action, or quality improvement in that system. The corrective action program compliments reporting systems such as CMCAP, NCR's, or Waste NCR's, by accessing those systems to identify corrective actions and tracking those corrective actions in the QCR data system. Quality Assurance engineers will serve as facilitators to all levels of management to implement the QCR process.

Please provide a review of Draft C of the Quality Condition Report (QCR) procedure. I would like your comments by September 15, 1996. I am serving as the subject matter expert on this procedure. Please feel free to obtain clarification or specific information by calling me at extension 4747.

TMP:

Distribution:

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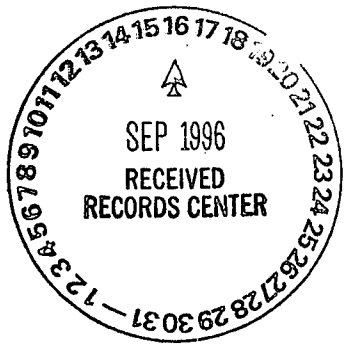
cc:
ESH&Q File
RMRS Records Center



ADMIN RECORD

1/15

REVIEW COMMENT SHEET

Time Spent on Review: Hrs.

Return to:

8225	Mic Prochazka	4747	T893B
FAX	Name	Ext.	Location

Questions on content are addressed to SME below:

Mic Prochazka	4747
SME Name	SME Ext.

Page of

Please review the attached procedure: RMRS-QA-03.01 (Doc. Number) 0 (Rev.) C (Dft.) Title Quality Condition Report

Comment Due Date **September 15, 1996**

DMR#

☐ **Internal Review** ☒ **Parallel** ☐ **Verification** ☐ **Concurrence** ☐ **Validation** ☐ **Revalidation**

General (G) comments require resolution but do not require resolution acceptance. Mandatory (M) comments require resolution and resolution acceptance. 1-A03-PPG-004 provides complete definitions of General and Mandatory comments.

TYPE G or M	PAGE	SECTION or LINE #	COMMENTS	DISPOSITION	Disposition accepted INIT/DATE

POC/Reviewer: (Comments not signed by POC will be considered unofficial and not subject to resolution

☐ This procedure has no impact or relevance to our discipline or organization and we waive the need to concur.
☐ No Comments
☐ Not Reviewed

Reviewer Name _____ Signature _____

Ext./Pager/Fax _____ Bldg./Dept./Director _____ Date

Resolution Accepted

Initials _____

Date

Note: These reviews are completed by qualified reviewers in accordance with 1-A03PPG-004 in concert with 1-A01-PPG-001 and 1-A02-PPG-003

RF-47947 (5/93)

REVIEW COMMENT SHEET (continued)

Please review the attached procedure: RMRS-QA-03.01 (Doc. Number) 0 (Rev.) C (Dft.) Title Quality Condition Report

TYPE G orM	PAGE	SECTION or LINE #	COMMENTS	DISPOSITION	Disposition accepted INIT/DATE

POC/Reviewer: (Comments not signed by POC will be considered unofficial and not subject to resolution

Reviewer Name _____ Signature _____ Date _____

Resolution Accepted

Initials _____

Date

3

QUALITY CONDITION REPORT

APPROVED:_____
Manager, Quality Assurance

1. PURPOSE

This procedure directs employees how to prepare the Quality Condition Report (QCR), analyze conditions and complete a response and corrective action. The procedure provides a means for RMRS to (a) report and improve processes or systems; (b) report and correct a process, activity, or system with a condition adverse to quality, or a significant condition adverse to quality.

2. SCOPE

This procedure applies to all RMRS employees, subcontractors and their facilities, projects, or programs. The personnel involved are the Originator who is the person identifying the deficient condition, the Responsible Manager (RM) who is responsible for corrective action, the Quality Engineer who serves as a Quality Facilitator (QF), and the Corrective Action Coordinator (CAC) who is the quality engineer responsible for managing the RMRS corrective action system. The QCR process is intended to complement processes already in place such as Stop Work (1-V10-ADM-15.02, Stop Work Action), Occurrence Reporting (1-D97-ADM-16.01, Occurrence Reporting Process), Nonconformance Reports (1-65-ADM-15.01, Control of Nonconforming Items), or Commitments Management (1-PO4-CMCAP-16.00, Commitments Management and Corrective Action Program). However, the QCR may be used to initiate these other processes when an employee is unsure which process should be used.

3. GENERAL REQUIREMENTS

3.1 An operation, process, equipment, item or system which does not meet documented requirements or does not satisfy anticipated quality, shall be promptly identified, reported, analyzed, and improved or corrected.

3.2 Management at all levels shall foster a "no-fault" attitude and encourage all personnel to participate in identifying conditions adverse to quality and suggesting improvements. Management shall document the results of internal surveillance, inspections, or management assessments, (self-evaluations) using the QCR.

3.3 All conditions adverse to quality and significant conditions adverse to quality shall be documented using the QCR process. The action to report a quality improvement, or self corrected deficient conditions will be documented using the QCR. The responsible manager will have 14 days to respond to a QCR or request an extension for up to 30 days. An extension request must include written justification. An extension request is not applicable to self corrected deficiencies.

3.5 Responsible managers at all levels shall use the QCR to document audit, assessment findings received from the DOE, EPA, CDPHE, or contracted auditing service. Findings may be attached to a QCR to satisfy this requirement.

4

3.6 Findings received from independent assessment (RMRS), performance oversight (K-H), shall be documented on the QCR. Findings not originally documented on a QCR may be attached to the form to satisfy this requirement.

4. DEFINITIONS

4.1 Condition Adverse to Quality
The condition observed does not meet documented requirements. Conditions include failures, malfunctions, deficiencies, defects, incorrect actions, or similar nonconformances.

4.2 Quality Improvement
The condition observed meets the requirements to perform work or process, or the item or equipment satisfies the requirements. However, the process, item, or equipment can be changed to Better the condition observed.

4.3 Self Corrected Deficient Condition
A deficient condition identified and corrected immediately by workers and management. Self corrected deficient conditions are credited as a continuous improvement items.

4.4 Significant Condition Adverse to Quality
The condition if uncorrected, could have a serious negative effect on safety, operability, product, process, or the environment. See Appendix 4 for the threshold evaluation of significant conditions adverse to quality.

5. RESPONSIBILITIES

All RMRS personnel shall meet the requirements of the QCR process and are encouraged to identify items or conditions adverse to quality. RMRS employees shall at the time of discovery of adverse conditions, initiate the QCR process and (a) takes those steps necessary to prevent or mitigate injury or loss, (b) and notify the responsible supervisor or manager.

5.1 Originator

The originator is a person who identifies an item or condition adverse to quality, or recognizes a need for corrective action or improvement. The originator is responsible for providing sufficient information about the condition as to allow for a prompt disposition. The originator is responsible for implementing a stop work due to safety concern.

5.2 Quality Facilitator

The Quality Facilitator (QF) is any RMRS quality engineer. The QF is responsible for facilitating the preparation, disposition and closure of a QCR. The QF shall enter QCR data in the RMRS Quality Data System (QDS) and verify completeness and correctness of QCR documentation.

5.3 Responsible Manager

The Responsible Manager (RM) has a salient understanding of the area, item or condition of concern. The responsible manager also has sufficient authority to achieve the needed actions to correct conditions adverse to quality and implement the requirements of the QCR process.

5

5.4 Corrective Action Coordinator

The Corrective Action Coordinator (CAC) is appointed by the QA manager to assure the proper control of all deficiencies, and quality improvements for RMRS. The CAC will support the quality facilitators and responsible manager to make timely resolution of deficiencies and improvements. The CAC is responsible for managing the QDS and provide timely reports to upper management.

6. INSTRUCTIONS

A Quality Improvement Hotline (966-4747) is available to assist RMRS personnel with the QCR process.

6.1 QCR Origination

The back of the QCR has the instruction for preparing the QCR. The originator will report such conditions to their supervisor or to a QF. When it is known at the outset that an NCR is needed, the condition may be documented on the NCR form.

Originator

1. Upon identification of a condition adverse to quality or need for improvement, complete the origination section of the QCR and forward the QCR to the quality facilitator.

2. If the originator determines that the deficient condition can be corrected immediately, and wants to take credit for the action taken, document those actions according to section 6.5.

Quality Facilitator

3. Evaluate the condition and determine if there is a nonconformance to a documented requirement. If no requirement is identified the condition can be addressed as a quality improvement in section 6.2.

4. If a requirement has been identified for a deficient condition, then perform the threshold evaluation for significant conditions adverse to quality in Appendix 4.

5. A condition adverse to quality is processed according to section 6.3.

6. A significant condition adverse to quality is processed according to section 6.4.

6.2 Quality Improvement

Quality Facilitator

1. Enter the QCR in the Quality Data System as a Quality Improvement.

2. Forward the QCR to the responsible manager with a response due within 14 days.

Responsible Manager

3. Contact the originator to discuss conditions and the recommended actions. Form a Quality Improvement Team (QIT), and develop suitable actions to achieve the improvement.

4. Document in the Action Party section the QCR those actions taken to achieve the established goal or improvement. Provide planned completion dates and actions taken. For a no action decision, provide written justification.

5. Forward the QCR with a completed response to the QF.

6. Implement the stated improvement.

Quality Facilitator

7. When actions are complete, close the QCR. Send a copy of the completed QCR to originator.

6.4 Condition Adverse to Quality

Quality Facilitator

1. Enter the proper quality codes in the QDS (see Appendix 1 for deficiency codes). Forward the QCR to the responsible manager with a response due in 14 days.

Responsible Manager

2. If necessary, contact the originator to discuss conditions and the recommended actions. Identify the cause and record in the Action section.

3. Document in the Action Section the QCR a corrective action plan and the tasks needed to complete a corrective action. Tasks that are initiated under the work control system must identify the IWCP number, and the task manager for the IWCP. Provide planned completion dates.

Note

If a determination is made that the condition is not going to be corrected, a written dispensation to the requirement must be obtained from the applicable governing authority, e.g., DOE for DOE Orders, etc.

4. Forward the QCR with a completed Action Party section to the QF.

5. Implement the stated corrective actions.

Quality Facilitator

6. Ensure the actions taken satisfy the approved corrective action plan.

7. The proper quality codes or cause codes should be verified and updated in the quality data system. Complete the close out block, then forward a copy of the QCR to the originator. (Refer to appendix 1 or 2 for deficiency codes and cause codes that apply to the QCR).

6.4 Significant Condition Adverse to Quality

Quality Facilitator

1. Contact the QA manager to determine if the significant condition adverse to quality will be

subject to Stop Work Action and proceed accordingly.

2. The quality facilitator will prepare documentation to enter the condition in the PATS system and provide the responsible manager the assigned tracking number.

Responsible Manager

3. Review the reported condition and take actions to prevent or mitigate injuries or losses. If the condition is determined to be a reportable occurrence, stop the QCR process and refer to Occurrence Reporting (1-D97-ADM-16.01, Occurrence Reporting Process). The manager also reviews conditions for Price Anderson reportability in accordance with the site system.

4. Perform root cause analysis.

5. Document in the Action Section the QCR a formal corrective action plan and the tasks needed to complete a corrective action. Task that are initiated under the work control system must identify the IWCP number, and the task manager for the IWCP. Provide planned completion dates.

6. Obtain quality assurance review and concurrence on the corrective action plan and supporting documentation.

7. Forward the QCR with a completed Action Party section to the QF.

8. Implement the stated corrective actions.

Quality Facilitator

9. Forward the corrective action plan to the PATS coordinator for DOE tracking. Be sure to include task managers and schedules for completion.

10. When all tasks are reported complete, ensure the actions taken satisfy the approved corrective action plan.

11. Complete the close out section, then forward a copy of the QCR to the originator.

6.5 Self Corrected Deficient Condition

NOTE: A significant condition adverse to quality is not eligible for action as a Self Corrected Deficiency.

Originator

1. Use the QCR to describe the condition noted, nonconforming requirement, and actions taken to correct it.

2. Sign, date, and submit the QCR to the QF.

Quality Facilitator

3. Enter the proper quality codes or cause codes in the quality data system. Provide a copy of the QCR to the originator.

8

7.0 RECORDS

The Quality Condition Report, (Example shown in Appendix 3) is a quality assurance record. Quality records are handled in accordance with the RMRS Records Program.

APPENDIX 1
QUALITY CONDITIONS
Based on DOE Criteria

The Quality Support person or qualified originator may review the Quality Condition Table and select the item that meets the description of finding. Write the statement in the quality condition field and enter the code number in the quality code block.

Criterion	Code	Quality Condition Value list
1. Quality Program		
	1.1	The organization has no formal Quality Assurance Program.
	1.2	The organization lacks structure, responsibilities, authorities, and lines of communication.
	1.3	Management lacks program for assessing quality of work.
2. Personnel		
	2.1	Personnel are not trained/qualified to perform assigned work or required to maintain proficiency.
	2.2	Training refresher or update is not scheduled or provided by Organization.
	2.3	Organization does not implement/maintain training and qualification records.
3. Quality Improvement		
	3.1	Organization has not developed or implemented an effective self-evaluation and inspection program.
	3.2	Organization does not have methods to identify, segregate, and provide corrective action or recurrence control.
	3.3	Organization does not have or use a formal data system for quality related problems.
	3.4	Organization does not have a formal process or equipment qualification program.
	3.5	Organization has not implemented a Total Quality Management Program.
4. Documents & Records		
	4.1	Document not prepared to plant standards.
	4.2	Document not reviewed, dispositioned, or approved properly.
	4.3	Document not controlled, revised or issued properly.
	4.4	Record not identified as quality record or administrative record.
	4.5	Record not prepared or submitted for record storage.
	4.6	Organization does not have or use adequate record storage facility.
	4.7	Inspection or test records are not complete.
5. Work Processes		
	5.1	Work plans, parameters or controls are not identified or used.
	5.2	Procedures do not comply with codes and standards.
	5.3	Process/equipment nor formally qualified or tested before use.
	5.4	Out of Control equipment not disabled or corrected by operator.
	5.5	Process or Equipment not operated by qualified personnel.
6. Design Control		
	6.1	Requirements/Quality standards not written into Specifications, Drawings etc.
	6.2	Unauthorized deviation from specifications, or standards.
	6.3	Review of safety function was not done.
	6.4	Identification & control of design review or interface not done.
	6.5	Verification & check of design not done or performed by independent.
	6.6	Design process does not use implementing procedure.
	6.7	Changes are not managed, approved or meet original design requirements.

10

APPENDIX 1 (continued)
QUALITY CONDITIONS
Based on DOE Criteria

Criterion	Code	Quality Condition Value list
7. Procurement		
	7.1	QA requirements, specifications, not identified in statement of work.
	7.2	QA requirements, specifications not identified for item purchased.
	7.3	Supplier does not have required QA Program.
	7.4	Purchaser does not assure adequate product or service.
	7.5	Quality of delivered product/service not evaluated or verified.
	7.6	Evidence not retained to show compliance.
8. Inspection		
	8.1	Activity not inspected to verify conformance.
	8.2	Inspection hold points not identified or used.
	8.3	Inspection method not identified, not followed, or inadequate.
	8.4	Inspection results not documented.
	8.5	Identity and control of rejected item not maintained.
	8.6	Inspection or Test Equipment not properly maintained, calibrated, or documented.
9 Management Assessment		
	9.1	Management has not planned, or scheduled periodic assessment of Quality program.
	9.2	Management did not identify problems that hinder objectives.
10. Independent Assessment		
	10.1	Management has not planned and implemented periodic independent assessments.
	10.2	Management did not use a technically knowledgeable and qualified assessor.

11

APPENDIX 2
CAUSE ANALYSIS WORK SHEET
To be used for all RMRS Cause Analysis

Cause Category	Code	Cause Code Value list
001 Equipment		
	1	Defective or failed part, material, equipment, hardware, software.
	2	Installation or maintenance incorrect.
	3	Wrong tool fixture used or substituted.
	4	Equipment in service beyond work cycle, life cycle expectation.
002 Communication		
	1	The correct terminology, or vocal repeat was not used.
	2	Conflicting verbal instruction or message.
	3	Labels, Signs, Written instruction unclear.
	4	Written or verbal instruction was not timely.
003 Management System		
	1	Procedure not provided or available.
	2	Preparation, review or management involvement not adequate.
	3	No corrective action system.
	4	Safety quality review at shift turnover inadequate.
004 Personnel		
	1	Human error.
	2	Not following procedure.
	3	Not capable or qualified to perform activity.
005 Procedure		
	1	Written procedure not available, Inadequate, or difficult to use.
	2	Wrong revision.
	3	Parameters/facts wrong.
006 Training		
	1	Training not available.
	2	Infrequent task had no walkdown or PRE-EV.
	3	Experience or OJT inadequate.
	4	routine activity changed without refresher or training update.
007 Work Environment		
	1	Poor lighting or ventilation.
	2	Work are access, clearance, or usability.
	3	Repetitive or strenuous task.
	4	Does not meet OSHA requirements.

APPENDIX 3
Quality Condition Report
Use for all RMRS Deficiencies

RMRS Rocky Mountain Remediation Services, L.L.C. . . . protecting the environment

QUALITY CONDITION REPORT

Report No.:
Page of
Issue date:
Response Due By:

ORIGINATOR	1 Date:	2 Bldg./Room	3 Originator Sign:	
4 Originator Notify Manager: ☐ YES ☐ NO			5 Originators Name:	Ext.
6 Responsible Manager & Org:		Org.	7 Dept:	

8 QPR Subject: Describe the condition. Include requirements if known.

QA ANALYSIS: Quality Code:	9 Quality Criterion	10 Deficiency Description	11 Significance screen
Cause Code:	12 PATS: ☐ Yes ☐ No	NO	Risk total

13 Reviewer's Name. _____ Signature: _____

14 *Quality Assurance Facilitator Identify Requirement(s):*

ACTION PARTY: 15 Identify contributing causes. If the QPR is a Significant Condition Adverse to Quality the Action Party must: perform Cause Analysis. (See Also Significant Condition Actions).

16 Prepare a Corrective Action Plan : Identify each task & manager. If the C/A uses IWCP, enter IWCP no. here and IWCP task manager below.

17 Corrective Action/Task Manager	Signature:	ORG:

18 Significant Condition Actions: ☐ Continued on Page 2

19 Task manager enter planned Completion	Date:			Initial
20 Task manager enter actual Completion	Date:	Signature:	Date:	
21 QA Facilitator verify & Initial concurrence:	Date:	Verifier's Name:		Initial

CLOSE OUT	Independent Verification:	Remarks:	Est. Savings Cost:
	Verifier's Name: Signed _____ Date _____		

RMRS-QPR-96 (4/96)

13

APPENDIX 3

QCR Instruction Page for RMRS-QA-03.01, Quality Condition Reports Rev. 0.

COMPLETE THE ORIGINATOR SECTION: Steps 1 through 8.

1 Enter the Date the deficient condition is first observed.
2 Enter the specific building location and room number.
3 The originator signs the QCR.
4 Check YES, if you have notified the responsible manager. Check NO, if the responsible manager is unknown or was unavailable.
5 Enter the originators name and phone extension.
6 Enter the name of the responsible manager and managers Organization number if known.
7 RMRS is divided into the four departments shown. Mark the department responsible for the condition noted.
8 Clearly state the condition observed. Additional text can be written on plain paper simply labeled SUBJECT CONTINUED. Optional: The originator has the option of identifying the type of condition noted.

COMPLETE QA ANALYSIS: *Steps 9 through 14*

9 Select the Quality Criterion, (ref. DOE Order 5700.6C, or 10CFR 830.120) to agree with the condition identified on the QCR.
10 Enter a Deficiency Description. The CAC may modify description and enter a deficiency code.
11 Perform a significance screen and enter the Risk Total. (see Appendix 5 for instructions).
12 Based on risk determine if QCR is submitted to PATS, and obtain PATS number.
13 Enter the name of the QCR reviewer, and sign the reviewer block. A risk total is 7 or higher constitutes a Significant Condition Adverse to Quality and must be forwarded to the QA Manager.
14 Review applicable references and write in the requirement and source for the responsible manager. The reviewer may obtain input from the originator.

NOTE

The Quality Facilitator will issue a QCR with a Response Due Date. If the responding manager cannot meet this schedule, an extension may be requested. The corrective action coordinator will review the request and extend the response up to 30 days.

COMPLETE ACTION PARTY: Steps 15 through 21

15 List any know or suspected contributing cause, and underline the cause with the greatest effect.
16 Prepare a corrective action plan with sufficient detail to preclude recurrence of the noted condition. Multiple tasks must be listed separately with and task manager and IWCP numbers.
17 Enter the corrective action manager's name. The C/A manager signs approval and organization code.
18 A significant condition may require a review of compliance to the Price Anderson Amendment.
19 Enter the planned completion date.
20 Enter the actual completion date. When all actions are complete the responsible manager signs the QCR and forwards to the facilitator for concurrence. If the planned date cannot be met, the task manager will contact the corrective action coordinator for an extension. The CAC will enter a new date based on justification.
21 The facilitator reviews documents that support completion, then dates and signs the QCR.

APPENDIX 4
SIGNIFICANT CONDITION THRESHOLDS

RMRS uses the DOE Handbook, Guidance for Identifying, Reporting and Tracking Nuclear Safety Noncompliances, DOE-HDBK-1089-95.

The following tables list the criteria for determining significant conditions adverse to quality. Determinations are based on significance to programmatic or management deficiencies, facility conditions, environmental impact, personnel radiation exposure, and failure of administrative actions.

TABLE OF THRESHOLDS FOR SIGNIFICANT CONDITIONS ADVERSE TO QUALITY

TYPE OF CONDITION	SIGNIFICANCE THRESHOLD
1. Programmatic or Management Deficiencies	Repetitive problem. Programmatic breakdown, lack of organization structure. Intentional violation. Significant management failure. Misrepresentation.
2. Facility Conditions	Nuclear Safety Controls. Potential Fire/Explosion. Safety status degradation. Loss of control of radioactive material or spread of contamination. Vital structure, System, Component degradation. Violation of procedures or inadequate procedure. Unsatisfactory surveillance or inspections. Operations
3. Environmental	Radionuclide release Hazardous material contamination
4. Personnel Radiation Exposure	Radiation exposure Personnel contamination
5. Administrative Actions	Failure to activate a site emergency plan as a result of a noncompliance issue or occurrence. Failure to complete a significant action as identified in a DOE approved Price-Anderson Amendments Acts (PAAA) Implementation Plan. Failure to meet a DOE PAAA Compliance Order. Failure to identify and/or report to DOE an unreviewed safety question.